

REMARKS

The above referenced application has been reviewed in light of the Office Action mailed January 21, 2009. Claims 1-9, 12-22, 24 and 25 are currently pending in this application with Claims 1 and 12 being in independent form. In view of the remarks to follow, reconsideration and allowance of this application are respectfully requested.

Claims 1-9, 12-22, 24, and 25 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In the Office Action, it is stated that the originally filed application does not include “the needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension “ x_t ” of the enlarged transition portion.” Specifically, the Examiner states that the language regarding the dimension of “ x_t ” can be interpreted to be the entire x-dimension of the enlarged transition portion, not just the difference of “ x_t ” and the enlarged transition portion, the Applicant should further clarify “ x_t ” to over the rejection.

The “ x_t ” dimension is, in fact, the entire x-dimension of the enlarged transition portion. The specification, on page 3, lines 18-19, recites that the “x-dimension and the z-dimension correspond to the height and width respectively of the needle end portion.” Accordingly, the recited “ x_t ” and “ x_l ” corresponds to the “ h ” and “ h_l ” as discussed in the specification. Further, as shown in FIG. 5, and described on page 7, the formed needle point is both displaced from the central axis extending through the center of the needle body and displaced from the lowest surface of the transition portion corresponding to a distance “ a .” Distance “ a ” is determined by angle “ α ” which ranges between about 2° and about 10° . As the specification does describe and show, the dimension “ x_t ” and the

displacement of the needle point, Applicants respectfully submit that the rejection of claims 1-9, 12-22, 24, and 25 under 35 U.S.C. §112 should be withdrawn.

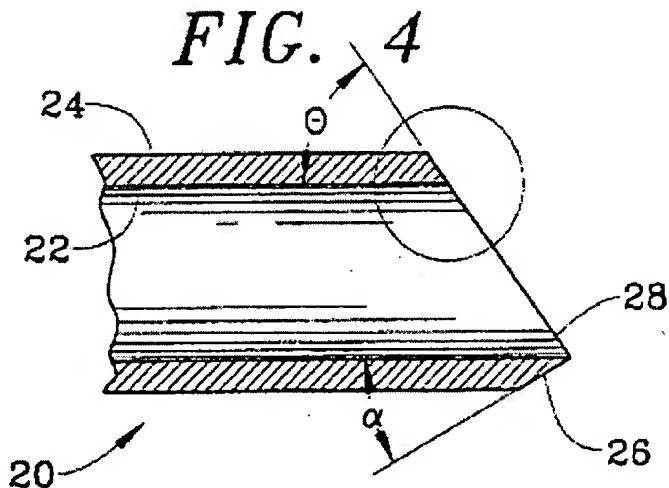
Claims 1-9, 12-22, 24 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,537,593 to Alchas in view of U.S. Patent No. 5,403,344 to Allen and U.S. Patent No. 5,733,266 to Gravlee, Jr. Applicants respectfully submit that Alchas, Allen, and Gravlee Jr., either alone or in combination, fail to teach or suggest the claimed apparatus and that there is no reason, motivation, or suggestion in Alchas, Allen, or Gravlee Jr. to combine the references.

As acknowledged by the Examiner, neither Alchas nor Allen teach a surgical needle including, *inter alia*, a “needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension ‘ x_t ’ of the enlarged transition portion, and at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10° , wherein the side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point,” as required by both independent claims 1 and 12.

The Examiner relies on Gravlee Jr. to cure the deficiencies of Alchas and Allen. Specifically, in the Office Action it is asserted that Gravlee Jr. teaches “the needle point (28) being displaced a predetermined distance with respect to the longitudinal axis (Fig. 4) and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension ‘ x_t ’ of the enlarged transition portion (Fig. 4),” and “at least one side of the needled end portion being displaced by an angle alpha from a plane parallel to the longitudinal axis (Fig. 4),

the angle being between about 2° , and about 10° , wherein the side of the needled end portion displaced by angle alpha from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point."

Gravlee Jr. discloses a hypodermic needle including a hollow shaft 20 having a substantially cylindrical inner surface 22 and a substantially cylindrical outer surface 24. The needle includes a beveled surface 26 extending between and connecting the inner surface 22 and the outer surface 24 of the hollow shaft 20. As illustrated in FIG. 4, reproduced hereinbelow, the beveled surface 26 forms a cutting edge 28 at the intersection between the beveled surface 26 and the inner surface 22 of the needle.



As shown in Fig. 4, and in contrast to the Examiner's assertions, Gravlee Jr. fails to disclose an enlarged transition portion. Additionally, Gravlee Jr. fails to disclose, *inter alia*, the side of the needled end portion having a substantially continuous slope between an enlarged transition portion and the needle point, as required by claims 1 and 12.

Moreover, the Examiner asserts that Gravlee Jr. teaches about 2° to about 10° as the word “about” includes more angles than 2°-10° (see the Response to Arguments section).

In contrast, Gravlee Jr. actually discloses that “[t]he angle α between the beveled edge 26 and the inner surface of the needle shaft is **about 15°** to **about 60°**, preferably about 40°.” (Emphasis added, see Gravlee Jr. at Col. 3, lines 42-44). The smallest angle disclosed in Gravlee Jr. (i.e., 15°) is **50% greater** than the largest angle that is claimed in claims 1 and 12 (i.e., 10°). While Applicants appreciate that the term “about” includes a greater amount than the value stated, Applicants do not think a reasonable interpretation of “about” includes a value that is more than 60% of the claimed range outside of the range. That is, the claimed range is about 8° (i.e., about 10° minus about 2°). The Examiner is asserting that the claimed range includes a value that is 62.5% of the range (i.e., $5^\circ/8^\circ * 100\%$) above the upper limit of the range. More particularly, Applicants respectfully submit that the claimed 8° range (i.e., about 2° to about 10°) cannot be interpreted to include a value (i.e., about 15°) that is more than 60% of the claimed range outside of the range. Additionally, Applicants respectfully submit that Gravlee Jr.’s range of about 15° to about 60° cannot be interpreted to include about 10° for at least the reasons discussed below.

With additional regard to Gravlee Jr., Applicants respectfully submit the Gravlee Jr. teaches away from the claimed range of about 2° to about 10°. In particular, Gravlee Jr. states that “[t]he beveling of the exterior edge of the hypodermic needle 20 according to the present invention provides a **smaller** and sharper point than the point of a conventional needle of the same diameter” and “[t]he **smaller area of cutting** causes

trauma to a smaller area of tissue" (see Col. 3, lines 50-61 of Gravlee Jr., emphasis added). Additionally, Gravlee Jr. recites, "due to the cutting edge 28 at the inner diameter of the needle, there is no jamming, pushing, or compression of tissue from the leading cutting edge into the bore of the needle" (see Col. 4, lines 3-6).

Thus, the purpose of the range of alpha angles in Gravlee Jr. is twofold: 1) to provide a small area of cutting; and 2) to help push excised tissue away from the bore of the needle.

As can be appreciated, reducing the lower limit of the alpha angle of Gravlee Jr. would have two effects: 1) it would effectively enlarge the size of the point of the hypodermic needle, thus creating a **larger** area of cutting; and 2) it would reduce the amount of excised tissue that is directed away from the bore of the needle. Thus, if the Examiner's proposed interpretation of Gravlee Jr.'s range of alpha angles were practiced, **two** functions of Gravlee Jr.'s hypodermic needle would be destroyed.

Accordingly, in contrast to the assertions in the Office Action, Gravlee Jr. fails to disclose or teach, *inter alia*, "the angle α being between about 2° and about 10°," as required by claims 1 and 12. In fact, and as discussed above, Gravlee Jr. actually teaches away from this claimed range. Accordingly, in view of the foregoing remarks/arguments, Applicants respectfully request withdrawal of the rejections of claims 1 and 12, as being unpatentable under 35 U.S.C. §103(a) over Alchas in view of Allen and Gravlee Jr.

Since claims 2-9, 16-17, 22, and 24, which depend from Claim 1, and Claims 13-15, 18-21, and 25, which depend from Claim 12, contain all of the limitations of Claims 1 and 12, respectively, for at least the reasons presented above regarding the patentability

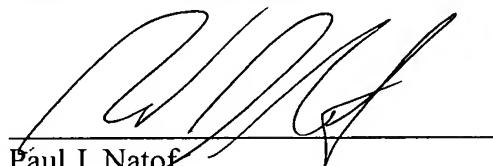
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of claims 1 and 12, Applicants respectfully submit that each of claims 2-9, 13-22, 24, and 25 is also patentable over Alchas in view of Allen and Gravlee Jr.

In view of the foregoing remarks, Applicants submit that all of the claims are in proper format and are patentably distinct from the references of record and are in condition for allowance. The Examiner is invited to contact the undersigned Attorney at the telephone number listed below with any questions concerning this application.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.

Respectfully submitted,



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